OCT - 5 2000

K001387

i-STAT
CORPORATION

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K 001387.

Summary Prepared on: 20 July 2000

Submitted by:

i-STAT Corporation
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Contact:

Paul VanDerWerf, Ph.D., Vice President Regulatory Affairs and Quality Assurance

Establishment Registration Number: 2245578

Identification of the Device:

Device Name:	i-STAT®[1] Model 300 Portable Clinical Analyzer
Proprietary/Trade Name:	i-STAT Portable Clinical Analyzer
Common Name:	Portable Clinical Analyzer
Classification Name:	See Table Below
Device Classification:	See Table Below
Regulation Number:	See Table Below
Panel:	See Table Below
Product Code:	See Table Below

[1] i-STAT is a registered trademark of i-STAT Corporation.

The table below summarizes the tests that have been cleared by K-numbers for use on the i-STAT Model 300 Portable Clinical Analyzer

Name:	Class:	Regulation Number:	Panel:	Product Code:
Electrode, Ion Specific, Sodium	II	862.1665	Clinical Chemistry	JGS
Electrode, Ion Specific, Potassium	II	862.1600	Clinical Chemistry	CEM
Electrode, Ion Specific, Chloride	II	862.1170	Clinical Chemistry	CGZ
Electrode, Ion Specific, Urea Nitrogen	II	862.1770	Clinical Chemistry	CDS
Glucose Oxidase, Glucose	II	862.1345	Clinical Chemistry	CGA
Hematocrit	II	864.6400	Hematology	JPI
Electrode, Ion Specific, Calcium	II	862.1145	Clinical Chemistry	JFP
Electrode Measurement, Blood-Gases (PCO_2, PO_2) And Blood pH	II	862.1120	Clinical Chemistry	CHL
Electrode, Ion Based, Enzymatic, Creatinine	II	862.1225	Clinical Chemistry	CGL
Acid, Lactic, Enzymatic Method	II	862.1450	Clinical Chemistry	KHP
Activated whole blood clotting time	II	864.7140	Hematology	JBP

Identification of the Predicate Device:

The predicate device is the MediSense Precision PCx™[2] Glucose Monitor.

Description of the new device:

The new device combines the features of the i-STAT Model 200 Portable Clinical Analyzer (PCA) with the glucose test strip processing capability of the MediSense Precision PCx Glucose Monitor. The main features that are combined in the i-STAT Model 300 PCA are:

- Utilization of i-STAT test cartridges.
- Utilization of MediSense glucose test strips.
- A bi-directional infrared communications port.
- A laser barcode reader.
- Battery powered devices for point-of-care

Intended use of the Device:

The i-STAT Model 300 Portable Clinical Analyzer is intended to be used by trained medical professionals for use with i-STAT test cartridges and MediSense blood glucose test strips. i-STAT cartridges comprise a variety of clinical chemistry tests and test panels.

Summary of Non-Clinical Test Performance in Support of Substantial Equivalence:

Laboratory testing by experienced operators has been carried out in order to demonstrate the performance of the i-STAT 300 glucose test strip system with respect to precision, dynamic range, linearity and environmental conditions. In demonstration of performance for the i-STAT

[2] MediSense and Precision PCx are trademarks of Abbott Laboratories Inc., Abbott Park, IL.

300 glucose strip reader, the MediSense Precision PCx glucose test strip system was used as the predicate device.

Experimental protocols were developed with reference to the National Committee for Clinical Laboratory Standards (NCCLS) guidelines. Laboratory testing of the i-STAT 300 glucose test strip system was designed to produce data to support compliance with the requirements of the Food and Drug Administration's guidance documents regarding Blood Glucose Testing Systems.

Day-to-day precision of the i-STAT 300 glucose test strip system was compared to that of the MediSense Precision PCx system. Precision was conducted on a total of eleven i-STAT Model 300 systems and six MediSense Precision PCx Monitors. Three levels of MediSense Precision Glucose Control Solutions (LOW, MID and HIGH) were tested.

Within run standard deviation (SD), within run coefficient of variation, mean, total standard deviation and total coefficient of variation were evaluated on the i-STAT 300 glucose test strip module and compared to the MediSense Precision PCx performance. The results summarized in Table 1indicate that the two systems are equivalent in performance for within-day, between-day, and between-meter precision.

Table 1. Precision of i-STAT Model 300 and MediSense Precision PCx.

CONTROL LEVEL TESTED	INSTRUMENT	MEAN	TOTAL SD
LOW	PCx	45.5	3.49
LOW	ISTAT 300	45.3	3.98
MID	PCx	84.60	5.88
MID	ISTAT 300	84.24	5.61
HIGH	PCx	270.75	12.91
HIGH	ISTAT 300	270.43	15.12

The linearity performance of the i-STAT 300 glucose strip reader was evaluated following a protocol designed to demonstrate that the i-STAT 300 reports glucose results on MediSense Precision PCx blood glucose test strips in an equivalent manner as compared to the MediSense Precision PCx across the dynamic (measurement) range (20 to 600 mg/dL) using donor blood samples spiked with glucose. Three lots of glucose test strips were utilized with each of three of each type of instrument.

The dynamic ranges of the i-STAT 300 glucose strip reader and of the MediSense Precision PCx were compared. The dynamic range for the glucose test strip for the MediSense Precision PCx and i-STAT 300 is 20 mg/dL to 600 mg/dL.

Ninety-six assays (48 samples tested in duplicate) for the linearity experiment were conducted on each of the three glucose test strip lots for each of the 8 whole blood specimen sets. Tests were evenly divided between the i-STAT and PCx systems. The results presented in Table 2.

Table 2. Linearity of i-STAT Model 300 Vs the MediSense Precision PCx Monitor.

Correlation Coefficient	Lot 116945	Lot 116355	Lot 116245	All Lots Combined
(r)	0.9920	0.9955	0.9951	0.9947
y-intercept	7.1	1.8	1.6	3.8
Slope	0.9530	0.9824	1.006	0.9785
Sy.x	15.7	12.2	11.8	12.6
N	89	92	90	271

Testing was also performed using samples that contained less than the lower limit of dynamic range (20 mg/dL) and samples that contained more than the upper limit of dynamic range (600 mg/dL). In all cases the instruments displayed the appropriate messages **< 20 mg/dL** or **>600 mg/dL.**

Clinically accurate results were obtained across the dynamic range for samples tested in the linearity protocol (20 – 600 mg/dL) using whole blood on the MediSense Precision PCX and the i-STAT 300 analyzers. The regression analysis for the i-STAT 300 system demonstrated good correlation and linearity when compared to the MediSense Precision PCX predicate analyzer.

Testing outside the dynamic range (<20 mg/dL, >600 mg/dL) demonstrated that the i-STAT 300 system can appropriately handle values at the low and high extremes of the testing range.

Six MediSense Precision PCx Glucose Monitors and six i-STAT Model 300 PCAs were tested at several combinations of temperature and humidity using a simulated test strip that delivered, at three levels, electronic signals. The results showed that there were no medically significant differences between the i-STAT Model 300 PCA and the predicate device at all conditions tested.

Summary of Clinical Test Performance in Support of Substantial Equivalence:

Venous blood samples were analyzed on Medisense glucose strips run on the Medisense PCx, the i-STAT Model 300 and a YSI glucose analyzer. The results are summarized in Table3 below.

Table 3. Summary of Regression Analysis.

X data	Y data	n	LMS Slope	LMS Intercept	Deming Slope	Deming Intercept	SD X	SD Y
YSI	i-STAT strip	81	0.9452	7.11	0.947	6.92	1.25	4.25
YSI	PCx strip	82	0.9236	8.32	0.924	8.17	1.6	5.92
PCx	i-STAT strip	82	1.026	-1.8	1.032	-2.4	5.3	4.3

Conclusions:

The i-STAT Model 300 Portable Clinical Analyzer is substantially equivalent to the MediSense Precision PCx blood glucose monitor with respect to the processing of blood glucose test strips.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 5 2000

Mr. Paul VanDerWerf
Vice President, RAQA
i-STAT Corporation
104 Windsor Center Drive
East Windsor, New Jersey 08520

Re: K001387
Trade Name: i-STAT Portable Clinical Analyzer (Model 300)
Regulatory Class: II
Product Code: CGA
Dated: September 8, 2000
Received: September 11, 2000

Dear Mr. VanDerWerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for use

510(k) Number (if known): K001387

Device Name: **i-STAT Portable Clinical Analyzer (Model 300)**

The i-STAT Analyzer is used by trained medical professionals for running a variety of clinical chemistry tests and test panels contained in i-STAT test cartridges. These tests include hematocrit, glucose, blood urea nitrogen, sodium, potassium, chloride, ionized calcium, blood gases (oxygen, carbon dioxide, and pH), creatinine, lactate and activated clotting time. It is also used by trained medical professionals to run glucose test strips manufactured by Abbott Laboratories for the purpose of monitoring blood glucose levels.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001387

(Please do not write below this line—continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)